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Audley A Ciamporcero Jr One Johnson & Johnson Plaza New Brunswick, NJ 08933-7003			EXAMINER	
			SOUAYA, JEHANNE E	
ART UNIT	PAPER NUMBER			
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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/673,445	HARVEY, WILSON
	Examiner Jehanne Souaya	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 April 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-19 and 22-25 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                    6) Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Applicant's election without traverse of Group I, claims 1-19 and 22-25 in Paper No. 7 is acknowledged. Claims 20-21 have been withdrawn from consideration. An action on the merits of claims 1-19 and 22-25 follows.

### ***Sequence Listing***

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. The application lacks sequence identifiers for each sequence listed in the specification. All recitations of sequences in the specification and the claims must be followed by a sequence identifier. Further, the application lacks a paper copy and a computer readable form of the sequences in a "SEQUENCE LISTING". Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R. § 1.821(g).

### ***Priority***

3. Applicants claim for priority to the GB application 9808202.7 is acknowledged. The instant claims have been awarded the benefit of the 4/17/1998 filing date of the 9809202.7 application as the subject matter of the instant claims is present in the 9808202.7 application.

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***Claim Objections***

4. Claim 8 is objected to because of the following informalities: the claim recites ‘either of’ in line 2, which is grammatically incorrect. The claim should recite “comprises either interleukin...”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

***Indefinite***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-19 and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-3 and 18 lack a positive process step relating back to the preamble. The claims recite in the preamble, a method of determining susceptibility of a patient to developing a chronic ulcer, or predicting the severity of a chronic ulcer or predicting the healing response of a chronic ulcer, but the last step recites determining the polymorphism type of a gene which encodes an inflammatory cytokine. Therefore, it is unclear if the methods are drawn to determining susceptibility, predicting severity or predicting healing response, or if the methods are drawn to detecting a polymorphism.

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B) Claim 14 is indefinite in the recitation in step b of “second (nested) amplification” as it is unclear if the term recited in the parentheses is a limitation in the claim or whether it is an example of a possible “second amplification” and the claim is not necessarily further limited to a second round of amplification which is nested amplification. Consequently, the metes and bounds of the claim are unclear.

***Enablement***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-19 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support determination that a disclosure does not satisfy the enablement requirements and whether any necessary experimentation is undue (See *In re Wands*, 858 F. 2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors include, but are not limited to:

*Quantity of Experimentation Necessary*

*Amount of Direction and Guidance*

*Presence and Absence of Working Examples*

*Nature of the Invention*

*Level of predictability and unpredictability in the art*

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Nature of the Invention

The claims are broadly drawn to methods of determining the susceptibility of a patient to developing a chronic ulcer or a dermal ulcer by determining any polymorphism type, and more specifically the +3953 IL-1B polymorphism and/or the -889 IL-1A polymorphism, of a patient in genes that encode inflammatory cytokines; to methods of predicting the severity of a chronic ulcer or a dermal ulcer in a patient by determining any polymorphism type, and more specifically the +3953 IL-1B polymorphism and/or the -889 IL-1A polymorphism, of a patient in genes that encode inflammatory cytokines; and to methods of predicting the healing response in a chronic ulcer or a dermal ulcer in a patient by determining any polymorphism type, and more specifically the +3953 IL-1B polymorphism and/or the -889 IL-1A polymorphism, of a patient in genes that encode inflammatory cytokines.

Amount of Direction and Guidance

The specification teaches at page 5, lines 21-23, “the inventors have noted an increased frequency of particular alleles in individuals in both population and family studies in connection with the incidence of sever chronic ulcers that do not heal”. However, the specification, does not teach the identity of these alleles. The specification further teaches at lines 23-25 “It has been found that there is a link between the polymorphism type of various genes that encode inflammatory cytokines in a patient and the risk that the patient may develop a chronic ulcer”. The specification, however, does not teach either the identity of the particular alleles from the specific inflammatory cytokine or whether these results were statistically significant. The

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specification teaches at page 8 “The presence of allele 2 of the Il-1A -889 polymorphism or allele 2 of the +3953 polymorphisms of the IL-1B gene is a positive indicator of susceptibility to chronic ulcers”. However the specification does not teach whether this assertion is based on the results of a study, or whether, as noted above, this assertion is based on a statistically significant finding. Further, the specification does not teach whether the recitation of “positive indicator” refers to a statistically significant value. Such a teaching is necessary for the skilled artisan to be able to determine whether a predictable correlation exists between a specific allele in a specific gene and chronic ulcers. It is noted that the art teaches that although a *tendency* towards a higher frequency of the TNF-C haplotype was found in patients with ulcerative colitis (UC), the result was not statistically significant (Bouma et al., Clin. Exp. Immunol., vol. 103, pp 391-396, 1996, see abstract). Therefore, given this disclosure by Bouma et al, the skilled artisan would have been taught that a specific allele could be found in a patient with a disease, but that without statistical analysis, it is unclear whether the presence of a particular allele with a specific disease was predictably correlated with said disease. With regard to the Il-1A -889 polymorphism and the +3953 IL-1B polymorphism, the specification also does not teach whether the “positive indicator” is with reference to the presence of both alleles in patients with chronic ulcers, or whether the alleles were found separately. Such a teaching is also essential for the skilled artisan to practice the invention without undue experimentation because the art teaches that certain polymorphisms in IL genes are not separately associated with UC or Crohn’s Disease (CD), but that a statistically significant association exists between the presence of *both* alleles and UC and

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CD (see Bioque et al., Clin. Exp. Immunol. 1995, vol. 102, pp 379-383, which teaches that while a IL-1B allele was not associated with either UC or CD, a statistically significant association was observed between patients with UC or CD and both the IL-1B allele and IL-1RA allele 2 - abstract). From the teachings in the specification, however, the skilled artisan would not be able to determine whether the IL-1A -889 polymorphism or the +3953 IL-1B polymorphism, or both are a "positive indicator" of chronic ulcers.

Presence and Absence of Working Examples

The specification provides no working examples of methods of determining the susceptibility of a patient to developing a chronic ulcer or a dermal ulcer by determining any polymorphism type, and more specifically the +3953 IL-1B polymorphism and/or the -889 IL-1A polymorphism, in genes that encode inflammatory cytokines; of methods of predicting the severity of a chronic ulcer or a dermal ulcer in a patient by determining any polymorphism type, and more specifically the +3953 IL-1B polymorphism and/or the -889 IL-1A polymorphism, in genes that encode inflammatory cytokines; nor of methods of predicting the healing response in a chronic ulcer or a dermal ulcer in a patient by determining any polymorphism type, and more specifically the +3953 IL-1B polymorphism and/or the -889 IL-1A polymorphism, in genes that encode inflammatory cytokines. Further, the specification does not teach of any specific polymorphism type that can be predictably correlated with the severity of a chronic ulcer or a dermal ulcer, or with the healing response of a chronic ulcer or dermal ulcer.

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Level of Predictability and Unpredictability in the Art

The claims are broadly drawn to an association between chronic ulcers or dermal ulcers and *any* polymorphism in *any* inflammatory cytokine in *any* population. The specification, however, does not provide sufficient guidance to one of skill in the art to practice the invention as claimed without undue experimentation and the unpredictability taught in the art does not remedy the deficiencies in the specification. It is noted that the specification does not provide any examples of a statistically significant correlation between any polymorphism in any inflammatory cytokine and chronic ulcers or dermal ulcers. A search of the pertinent art revealed that while some studies teach that certain inflammatory cytokine polymorphisms are associated with ulcerative colitis (see Mansfield et al., *Gastroenterology*, 1994, vol. 106, pp 637-642,), such teachings have not been reproducible in subsequent studies. For example, although Mansfield teaches (abstract) that a statistically significant correlation was found between the presence of allele 2 of interleukin-1 receptor antagonist and patients with ulcerative colitis vs healthy controls, Hacker et al (*Gut*, vol. 40, pp 623-627, 1997) teaches that no significant differences were found between the presence of this allele and patients with either ulcerative colitis or Crohn's disease, both diseases involving chronic ulcers. With regard to other inflammatory cytokines, the art teaches that some polymorphisms in genes encoding inflammatory cytokines are not linked to either UC or CD. For example, Crusius et al., (*Gastroenterology*, vol 114, no. 4 supp, page g3924, 4/15/1998) teach that while IL-10 is critical in controlling the balance between inflammatory and humoral responses and that IL-10 deficient mice have been shown to develop

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inflammatory bowel disease with features of human CD, no evidence was found for the involvement of the IL-10 gene to overall susceptibility to CD or UC (see table, no significant difference between allele frequencies and patients with CD or UC vs healthy controls in a Dutch population). Further, a search of the pre filing and post filing date art revealed no guidance that any polymorphism in a gene encoding any inflammatory cytokine could be predictably correlated with susceptibility to chronic ulcers or dermal ulcers, the severity of chronic ulcers or dermal ulcers, or the healing response of chronic ulcers or dermal ulcers. The post filing date art also does not teach of any association between either the IL-1A -889 polymorphism or the IL-1B +3953 polymorphisms or both, in any population of patients with either chronic ulcers or dermal ulcers.

Quantity of Experimentation Necessary

Due to the unpredictability taught in the art with regard to polymorphisms in genes encoding inflammatory cytokines and patients with chronic ulcers and the lack of guidance from the specification as to any working examples or a statistically significant association between specific polymorphisms in genes encoding a specific inflammatory cytokine and patients with chronic ulcers or dermal ulcers or the severity of or healing response of said ulcers, the skilled artisan would be required to perform undue experimentation to practice the invention as claimed. To practice the invention as claimed, the skilled artisan would have to perform a large study of patients with chronic ulcers or dermal ulcers and controls to determine whether a predictable correlation exists between the presence of any polymorphism in a gene encoding any

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inflammatory cytokine or more specifically, the IL-1A -889 polymorphism or the IL-1B +3953 polymorphisms or both, and susceptibility to, severity of, or healing response of chronic or dermal ulcers. Given the unpredictability taught in the art with regard to polymorphisms in genes encoding inflammatory cytokines and an association with chronic ulcers, and the lack of guidance from either the specification or the art with regard to an association between a specific polymorphism and the severity of or healing response of a chronic ulcer or dermal ulcer, such experimentation would require trial and error, the results of which are unpredictable. The claims merely provide the skilled artisan with an invitation to experiment and the specification provides no guidance as to a predictable correlation between the association of a polymorphism in a gene encoding an inflammatory cytokine and patients with chronic or dermal ulcers. Further, the art teaches the unpredictability of an association between specific inflammatory cytokine polymorphisms and patients with chronic ulcers, even in genes encoding inflammatory cytokines that have been implicated in diseases (IBD) characterized by chronic ulcers. Therefore, given a) the quantity of experimentation necessary and that such experimentation requires trial and error, b) that the guidance from the specification only provides the skilled artisan with an invitation to experiment, and c) results of the trial and error analysis required by the skilled artisan are unpredictable, the skilled artisan would have to perform undue experimentation to practice the invention as claimed.

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***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3, 6-8, 12-13, 15, 17-19, 22, and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by Plevy et al., (WO 97/39147).

With regard to claims 2-3, and 18, it is noted that the claims only recite a positive process step of detecting a polymorphism in an inflammatory cytokine, therefore the claims have been broadly interpreted to encompass the teachings of Plevy. Plevy teaches detecting a haplotype consisting of TNF-a polymorphisms in nucleic acid samples from peripheral blood (p. 22, line 14) in patients with CD (see example 2). Plevy teaches (see claim 21) that nucleic acid can be analyzed by preparing a nucleic acid comprising TNF locus DNA with either a restriction enzyme (see claim 25) or by PCR (see claim 22) and contacting with a polymorphism specific probe. Plevy teaches the use of P<sup>32</sup> labeled probes (see p. 25, line 7).

11. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bioque et al (Clin. Exp. Immunol. Vol. 102, pp 379-383, 1995).

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With regard to claims 2-3, and 18, it is noted that the claims only recite a positive process step of detecting a polymorphism in an inflammatory cytokine, therefore the claims have been broadly interpreted to encompass the teachings of Bioque. Bioque teaches detecting allelic polymorphisms in the IL-1b and Il-1RA genes in patients with UC and CD (see abstract, and p. 380, col. 2).

12. Claims 1-3 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouma et al., (Clin. Exp. Immunol. Vol. 103, pp 391-396, 1996).

With regard to claims 2-3, and 18, it is noted that the claims only recite a positive process step of detecting a polymorphism in an inflammatory cytokine, therefore the claims have been broadly interpreted to encompass the teachings of Bouma. Bouma teaches detecting a statistically significant association between a polymorphism at position -308 in the TNF-a gene and patients with UC (see abstract and p. 392, col. 2).

***Claim Rejections - 35 USC § 103***

13. Claims 14, 16, 23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Plevy et al., (WO 97/39147) in view of Williams et al (Tissue Antigens, vol. 49, pp 129-133, 1997) and Tahar et al., (Transactions of the Royal Society of Tropical Medicine and Hygiene, 1997, vol. 91, p 410, abstract only).

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Plevy teaches detecting a haplotype consisting of TNF-a polymorphisms in nucleic acid samples from peripheral blood (p. 22, line 14) in patients with CD (see example 2). Plevy teaches (see claim 21) that nucleic acid can be analyzed by preparing a nucleic acid comprising TNF locus DNA with either a restriction enzyme (see claim 25) or by PCR (see claim 22) and contacting with a polymorphism specific probe. Plevy teaches the use of P<sup>32</sup> labeled probes (see p. 25, line 7).

Williams teaches a method of using digoxigenin labeled probes in conjunction with PCR to detect specific polymorphisms in HLA sequences (see abstract). Williams teaches detecting the probes using chemiluminescence (see p. 130, lines 1-2 of last para in col. 1).

Tahar teaches that the sensitivity of a PCR assay to detect a specific gene was improved by using a secondary nested PCR (see abstract).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to improve the method taught by Plevy to include a secondary nested PCR reaction as taught by Tahar to improve the sensitivity of the method of detecting TNF polymorphisms taught by Plevy. The ordinary artisan would have been motivated to add a secondary nested PCR in the method of Plevy because Tahar teaches that secondary nested PCR improves sensitivity. It would have further been *prima facie* obvious to one of ordinary skill in the art to use digoxigenin labeled probes as taught by Williams in the method taught by Plevy because the ordinary artisan would have recognized that using digoxigenin labeled probes would be equivalent to using P<sup>32</sup> labeled probes in a method of detecting hybridized probes. The

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ordinary artisan would have been motivated to use digoxigenin labeled probes because the detection of digoxigenin labeled probes would not have required the use of radioactive isotopes as taught by Plevy.

14. Claims 12-19 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bioque et al, or in the alternative, Bouma et al, in view of Plevy et al, and further in view of Williams et al and Tahar et al.

Bioque teaches detecting allelic polymorphisms in the IL-1b and Il-1RA genes in patients with UC and CD (see abstract, and p. 380, col. 2). Bioque teaches isolating nucleic acid from the peripheral blood of subjects.

Bouma teaches detecting a statistically significant association between a polymorphism at position -308 in the TNF-a gene and patients with UC (see abstract and p. 392, col. 2). Bouma teaches isolating nucleic acid from the peripheral blood of subjects.

Plevy teaches detecting a haplotype consisting of TNF-a polymorphisms in nucleic acid samples from peripheral blood (p. 22, line 14) in patients with CD (see example 2). Plevy teaches (see claim 21) that nucleic acid can be analyzed by preparing a nucleic acid comprising TNF locus DNA with either a restriction enzyme (see claim 25) or by PCR (see claim 22) and contacting with a polymorphism specific probe. Plevy teaches the use of P<sup>32</sup> labeled probes (see p. 25, line 7).

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Williams teaches a method of using digoxigenin labeled probes in conjunction with PCR to detect specific polymorphisms in HLA sequences (see abstract). Williams teaches detecting the probes using chemiluminescence (see p. 130, lines 1-2 of last para in col. 1).

Tahar teaches that the sensitivity of a PCR assay to detect a specific gene was improved by using a secondary nested PCR (see abstract).

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made that either the method of Bouma or Bioque could be improved using the nucleic acid preparation and detection methods taught by Plevy because the ordinary artisan would have recognized that using allele specific probes to detect polymorphisms would be more sensitivity than using electrophoresis to determine the size of amplification products. Further, the ordinary artisan would have recognized that allele specific probes would be preferable than amplification product sizes in determining the identity of a polymorphism when the alternate polymorphisms detected do not result in differently sized products, but rather are differences in nucleic acid sequence.

It would have further been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to improve the method taught by Bouma & Plevy or Bioque & Plevy to include a secondary nested PCR reaction as taught by Tahar to improve the sensitivity of the method of detecting TNF polymorphisms taught by Plevy. The ordinary artisan would have been motivated to add a secondary nested PCR in the method of Bouma & Plevy or Bioque & Plevy because Tahar teaches that secondary nested PCR improves sensitivity. It would have

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further been *prima facie* obvious to one of ordinary skill in the art to use digoxigenin labeled probes as taught by Williams in the method taught by Bouma & Plevy or Bioque & Plevy because the ordinary artisan would have recognized that using digoxigenin labeled probes would be equivalent to using  $P^{32}$  labeled probes in a method of detecting hybridized probes. The ordinary artisan would have been motivated to use digoxigenin labeled probes because the detection of digoxigenin labeled probes would not have required the use of radioactive isotopes as taught by Plevy.

***Conclusion***

15. No claims are allowable.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jehanne Souaya*

Jehanne Souaya  
Patent examiner  
Art Unit 1634

*June 26, 2002*